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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,058	04/15/2004	Robert Falotico	CRD-5079 NP	9477

27777 7590 07/28/2008  
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EXAMINER
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HAGOPIAN, CASEY SHEA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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07/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/826,058	<b>Applicant(s)</b> FALOTICO, ROBERT	
	<b>Examiner</b> Casey S. Hagopian	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of applicant's Amendment/Remarks filed 4/2/2008.

Claim 1 has been amended and Claim 5 has been cancelled. Thus, claims 1-4 are currently pending.

### **MAINTAINED REJECTIONS**

The following rejection has been maintained from the previous Office Action dated 1/4/2008:

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-4 stand rejected under 35 U.S.C. 102(a/e) as being anticipated by Hsu (US 2004/0037886 A1).**

It is noted that the instant claims are product claims and any intended use recitation, such as “for the treatment of atherosclerotic vulnerable plaque” in claims 1-4, “configured to maintain vessel patency and to provide structural support for a fibrous cap of a vulnerable plaque lesion” in claim 1, or “for treating at least one of the fibrous

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cap..." also in claim 1, does not alone show patentable distinction. A recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In other words, if the prior art structure is capable of performing the intended use, then it meets the claim.

Hsu teaches drug eluting coatings for medical devices, said coatings contain at least one therapeutic agent dispersed in biologically active binders (abstract). One particular embodiment described by Hsu is a medical device comprising at least one coating layer which contains at least one therapeutic agent dispersed in the biologically active binder and a cap coating (claim 17). Said cap coating comprises polymers (claim 23). Said therapeutic agents are chosen from the group consisting of paclitaxel, sirolimus (rapamycin), tacrolimus, everolimus, actinomycin-D, dexamethasone, mycophenolic acid, cyclosporins, estradiol, and combinations thereof (abstract; paragraph [0023]; claim 22). Said medical devices taught include balloon expandable stents and self-expanding stents (paragraph 0013; Examples).

It is noted that estradiol is a synonym for 17 beta estradiol and beta estradiol and sirolimus is a synonym for rapamycin as evidenced by The Merck Index.

According to MPEP § 2131.02, it is further noted that the therapeutic agent Markush group taught by Hsu also reads on the particular combination of "a rapamycin and 17 beta-estradiol". MPEP § 2131.02 states,

*In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978), claims to a specific compound were anticipated because the prior art taught a generic formula embracing a limited number of compounds closely related to each other in structure and the properties possessed by the compound class of the prior art was that disclosed for the claimed compound. The broad generic formula seemed to describe an infinite number of

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compounds but claim 1 was limited to a structure with only one variable substituent R. This substituent was limited to low alkyl radicals. One of ordinary skill in the art would at once envisage the subject matter within claim 1 of the reference.).

Because Hsu teaches a finite group of compounds and combinations thereof, one of ordinary skill in the art would at once envisage the particular combination of “a rapamycin and 17 beta-estradiol”. Thus, Hsu anticipates the instant claims.

### ***Response to Arguments***

The cancellation of claim 5 renders the objection and rejection under 35 USC 102 moot and therefore said objection and said rejection have been withdrawn for said claim.

Applicant's arguments with regard to the rejection of claim 1-4 under 35 USC 102 over Hsu have been fully considered but they are not persuasive.

Applicant argues that at Figure 68 and paragraphs [0278]-[0280] of the published application provide evidence that the combination of the two compounds is more effective than either drug alone. Applicant also argues that Hsu discloses a laundry list of compounds and does not disclose the specific combination.

In response, it is respectfully submitted that the examiner has reviewed the portions of the specification that applicant believes support for an unexpected result can be found. Said portions of the specification are concerned with the combination of Panzem® and sirolimus. Sirolimus is known as a synonym for rapamycin and Panzem® is known as 2-methoxyestradiol or methoxy-beta-estradiol which is a

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metabolite of 17-beta estradiol or estradiol. See paragraph [0478] of the published application. Panzem® is not 17-beta estradiol. The claims are currently drawn to the combination of rapamycin and 17 beta-estradiol, thus Figure 68 and paragraphs [0278]-[0280] are only applicable to the combination of Panzem® and sirolimus, not the claimed combination of rapamycin and 17 beta-estradiol. Thus the evidence provided is not commensurate in scope with the current claims.

It is further respectfully submitted that Hsu teaches 9 compounds, 2 of which are rapamycin and estradiol, which can be used in combination with one another (paragraph [0023]. Contrary to applicant's assertion, Hsu clearly does not disclose a laundry list of compounds. Rather, Hsu teaches a finite number of compounds. As discussed in the rejection above, MPEP 2131.02 explains that claims to a specific compound may be anticipated if the prior art teaches a generic formula embracing a limited number of compounds. Hsu teaches a limited number of compounds and combinations thereof, thus according to MPEP 2131.02, Hsu anticipates the claimed combination.

For these reasons, applicant's arguments are not persuasive. Thus, the rejection of claims 1-4 under 35 USC 102 over Hsu is maintained.

### ***Pertinent Art***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hossainy et al. (US 2003/0104028 A1) teaches stents that are coated with a polymer and a therapeutic substance (abstract). Claims 4 and 15 teach the particular therapeutic agents, estradiol and rapamycin.

Hossainy et al. (US 2005/0287184 A1) teaches stents coated with a polymer and the particular combination of estradiol and rapamycin (claims 1-6).

Llanos et al. (US 2005/0004663 A1) teaches coated stents, the coating comprising at least one therapeutic agent and a polymer (claim 1). Llanos also teaches the particular combination of 17 beta estradiol and rapamycin (paragraph 0492).

Fennimore (US 20050232964 A1) teaches a drug eluting medical device comprising a stent and a coating comprising a polymer and a therapeutic agent (claims 10-13). Fennimore also teaches the particular combination of 17 beta estradiol and rapamycin (paragraph 0486).

### ***Conclusion***

All claims have been rejected; no claims are allowed.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey S Hagopian/

Examiner, Art Unit 1615

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1615